chloro derivative, a fluorinated hydrocarbon, an acetate" is found throughout the specification and particularly on pages 30, lines 22-23, page 31 line 1, page 19 lines 1-11, page 24 line 26, page 28 line 7, and claim 18. The phrase "at a pressure of 0 to 10 bar" of new claim 81 is supported by the specification, and recited, for example, in claim 25. In claim 82, the recitation of increasing "the density of the column contents ... by increasing the column back pressure" is supported on page 40, lines 21 to 22. The phrase "temperature of the column contents during the step of passing the extract through the packed column is increased" of claim 83 is supported on page 40, lines 20 to 21. The phrase "gradient of methanol in carbon dioxide" of claim 84 is supported throughout and, particularly, on page 41, lines 4-6 and 16-18, and on page 35, lines 3-4. The phrase "isopropyl amine and methanol" of claim 85 is described, for example, on page 40, lines 23-25. The phrase NH2 column of claim 86 is described, for example, on page 39, line 21. The phrase "Kava root" of claim 87 and "Kava" of claim 98 are described, for example, on page 36, line 23. The terms "grinding or crushing" and "crushing, macerating, or mixing an herb or plant with a solvent" of claim 89 and 90 are supported on page 19, line 12, and page 20, lines 3-4. The terms "batch wise", "continuous-cascading extraction, or as a countercurrent-solvent extraction" of claims 92 and 95 are described on page 20, lines 10-11. The phrase "countercurrent mechanical presses" is supported by a description on page 18, lines 7-8.

Remarks Regarding 35 U.S.C. § 102(b)

Claims 17 and 18 stand rejected, under 35 U.S.C. § 102(b), as allegedly anticipated by Caster (U.S. Patent No. 5,440,055; "Castor 055"). Applicant respectfully traverses this rejection.

It is alleged that Example 5 and Example 6 of Castor 055 disclose the aspects of claim 17 and 18. Applicant respectfully disagrees. The taxol that was selectively stripped "out of the critical fluid phase" did not enter that fluid phase by a process as claimed in the present pending claims. Caster's starting material for the column procedure cited in Example 5 and Example 6 was not a "natural source substance" as claimed in the present invention. Instead, Castor's material that became treated to a supercritical fluid and placed on a column as described here, was not natural at all but had been purified.

Caster 055 describes a method that is limited to a two step procedure, which requires a first purification of taxol by a first critical fluid dissolution of undesired "waxes and other constituents of the source material" followed by addition of a "second fluid ... formed by combining a polar cosolvent such as methanol, ethanol, or acetone, with a CoNC fluid" and

"[T]he second fluid removes taxol and other taxoids from the source material." (see column 7 lines 16-33). The material that Caster 055 exposed to the polar cosolvent and placed on a column thus was not a "natural source substance" in any of his examples because all required purification before anything even remotely similar to the claimed method could be carried out.

The taxol of Caster's examples 5 and 6 was prepared by an extensive preparation including a previous supercritical extraction, as described in example 1. In particular, samples had to be dried before any processing took place because "critical fluid extraction was impeded by the presence of water in the needles" (column 15 lines 58-60). In particular "polar waxes did impede taxol mass transfer" (column 16 lines 35-36) and "[c]onsequently, subsequent experiments were conducted with a minimum of 100 sample volumes of critical fluid solvent on either hexane-washed or supercritical fluid carbon dioxide (SCF CO2) extracted needles. SCF CO2, ... behaves very much like hexane extracting about 7% of the polar waxes from the needles and no taxol." Thus Castor 055 gives a reason and a clear statement that all samples than might have been applied to any column had been extensively processed first. The claimed invention thus lacks Castor's first supercritical extraction step and is not anticipated.

The Castor 055 obligatory two step process is required to remove waxes and other contaminants that interfere with dissolution and purification of taxol prior to the step that is compared with the present claimed invention. In contrast, the one step one-supercritical process of the present claimed invention of claims 17-20 and 79-98 lacks treatment with an organic solvent or supercritical fluid followed by removal of contaminants to purify the material prior to adding to a column. The reference does not anticipate the claims because the claim term "contained in an extract" means contained in a plant material that has been, at most, prepared by an optional mechanical process such as grinding, crushing (page 19, line 12 of the specification) and maceration (page 20, line 3).

The extract described in the present specification and in claims 17 and 18 is a plant extract, not a partially purified chemical mixture or material that has been chemically processed to remove water and wax. To emphasize the difference of the claimed single supercritical fluid process from the two supercritical fluid process, new claims 79-98 have been added that recite permutations of using the one supercritical fluid process.

Thus, the rejection of claims 17 and 18, under 35 U.S.C. § 102(b), is overcome and applicant respectfully requests that it be withdrawn.

Remarks Regarding 35 U.S.C. § 102(e)

Claims 17 and 18 stand rejected, under 35 U.S.C. § 102(e), as allegedly anticipated by Caster (U.S. Patent No. 5,750,709; "Castor 709"). Applicant respectfully traverses this rejection.

It is alleged that Examples 5 and 6 of Caster 709 (a continuation in part of Castor 055) anticipates claims 17 and 18. Applicant respectfully disagrees. These examples mirror and concern the same procedure as those in Castor 055 and the same arguments are made as above. Caster 709, in each instance, describes and exemplifies a two step process where a first supercritical fluid is used to purify a plant substance, followed by a second supercritical fluid used to obtain the substance. The second supercritical fluid was applied to a column in two examples. Applicant's claimed method on the other hand begins with a material that has not been purified yet and subjects that material to a single supercritical fluid step.

The procedure used in the claimed invention thus has major claimed differences that allow the use of only a single type of hypercritical solution for the process, which greatly lowers costs, as mentioned on page 17, lines 19-24 of the specification.

Thus, the rejection of claims 17 and 18, under 35 U.S.C. § 102(e), is overcome and applicant respectfully requests that it be withdrawn.

Remarks Regarding 35 U.S.C. § 103

Claims 17-20 stand rejected, under 35 U.S.C. § 103, as allegedly obvious over Lopez-Avila and Schwabe (U.S. Patent No. 5,296,224), in view of Castor 055 and Castor 709. Applicant respectfully traverses this rejection.

None of these references, either singly or in combination describe the claimed method of taking a natural source substance, and passing that natural source substance through a column that has been treated with at least one volatile substance in a near-critical or supercritical state. In each example, a taxol containing biological material is processed by a chemical procedure to generate a chemically processed product. The claimed invention does not employ this step and actually is a great improvement for this very reason. Accordingly, a prima facie obviousness case is not met and it is respectfully requested to remove this rejection.

In addition to the above argument, applicant notes that Schwabe describes straightforward chemical extraction procedures that stress "water solubility" (abstract line 4) and leads away from the use of a lipid dissolving supercritical fluid, as used in the present claimed invention. The Schwabe and Lopez-Avila references fail to supply the missing element in the

Castor references by failing to show direct application of a natural material to a column that has been treated with a supercritical fluid. Accordingly a prima facie case is not established and withdrawal of the rejection respectfully is requested for this reason as well.

Thus, the rejection of claims 17-20, under 35 U.S.C. § 103, is overcome and applicant respectfully requests that it be withdrawn.

Conclusion

The application is in condition for allowance and the prompt issuance of a Notice of Allowance is respectfully requested. If there are any additional fees associated with the filing of this Amendment, not otherwise accounted for herein, the undersigned respectfully requests that any and all such fees, including any fees for an extension of time, be charged to Deposit Account No. 08-1641.

Respectfully submitted

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Date: May 21, 2002

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